

US Serial No. 09/778,168  
Response to Paper No. 0305

### REMARKS

#### Claim Rejections – 35 USC §103

Claims 1, 3-5, and 7-17 were rejected as obvious over Caskey in view of Fauser. Claims 6 and 18-22 were rejected as obvious over Caskey in view of Fauser and in further view of Whitcombe. Applicants respectfully traverse.

The cited references do not teach or suggest the presently claimed invention. The present Office Action cited to Caskey at column 8, lines 17-21 for the teaching of an isothermal amplification reaction. Applicants respectfully submit that the cited passage is being taken out of context. The cited passage merely states the activity level of a certain DNA polymerase. It does not teach an isothermal amplification reaction. Similarly, Fauser used a non-isothermal (PCR) amplification reaction.

Although Whitcombe mentions Strand Displacement Amplification, it does not cure the deficiencies of Caskey and Fauser. As argued in the Response to Paper No. 0804 of the present application, it is respectfully submitted that the prior art (Kwok et al., 1990, *Nucleic Acids Research* 18:999-1005) teaches away from the claimed invention. In particular, Kwok states in his abstract:

“We investigated the effects of various primer-template mismatches on DNA amplification of an HIV-1 gag region by the polymerase chain reaction (PCR). **Single internal mismatches had no significant effect on PCR product yield [i.e., primer extension occurs normally]** while those at the 3' terminal base had varied effects.” (emphasis added)

Kwok further states on page 1003, first column:

“In the process of generating templates with altered bases, we demonstrated that a single mismatch 3 residues from the 3' terminal base of a primer can be efficiently extended without modification of amplification reaction conditions. **Similarly, mismatches 1, 2, or 3 bases from the 3' nucleotide of primer had no apparent effect on overall PCR product yield.[i.e., primer extension occurs normally]**” (emphasis added)

Kwok is an article from a peer reviewed journal which describes actual experiments which demonstrate that a diagnostic nucleotide near the 3' end has no effect on product yield.

US Serial No. 09/778,168  
Response to Paper No. 0305

**Conclusions**

The claims of the present application are believed to be in condition for allowance, and early notice thereof is respectfully requested.

Respectfully submitted,



Allan M. Kiang  
Attorney for the Applicant  
Registration No. 42,275

Becton Dickinson and Company  
1 Becton Drive, MC089  
Franklin Lakes, New Jersey 07417  
(410) 316-4724

doc#92771